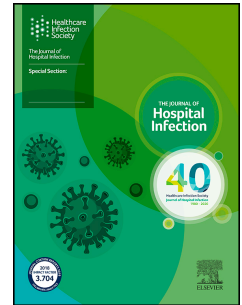# Journal Pre-proof

Overview of tight fit and infection prevention benefits of respirators (filtering face pieces, FFP)

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1   **Overview of tight fit and infection prevention benefits of respirators (filtering**

2   **face pieces, FFP)**

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24 **Summary**

25 Regulations for measures to protect against SARS-CoV-2 transmission vary widely around the world,

26 with very strict regulations in Germany where respirators (FFP2 or comparable) are often mandatory.

27 The efficiency of respirators, however, depends essentially on the tight facial fit avoiding the bypass of

28 contaminated air via gaps between mask and wearer's face. The facial fit can be verified in a fit test.

29 The aim of this review was to describe the quantitative fit test results depending on the respirator

30 designs. A literature search revealed 29 suitable studies. Of all respirators with circumferential head

31 straps, three-panel folded dome shaped respirators showed the best fit (80.8% of 4625 fit tests

32 passed), followed by rigid dome shaped respirators (72.4% of 8234 fit tests passed), duckbill shaped

33 respirators (31.6% of 2120 fit tests passed), and coffee filter shaped respirators (30.9% of 3392 fit tests

34 passed). Respirators with ear loops showed very poor tight fit (3.6% of 222 fit tests passed). In four

35 randomized controlled trials, single use respirators were not shown to be superior to surgical masks

36 for the prevention of laboratory-confirmed viral respiratory infections, even when adjusted with a fit

37 test. Therefore, we consider the mandatory use of respirators to be disproportionate and not

38 supported by evidence. Further evidence should be generated, in which scenarios respirators might

39 provide an effective benefit as part of occupational health and safety. For situations with confirmed

40 benefits only high quality disposable respirators with head straps or respiratory protective equipment

41 of higher protective levels should be used.

42   **Introduction**

43   Particle-filtering face pieces (FFP) are disposable half mask orinasal respirators (nonreusable, NR)

44   which are generally used as part of personal protective equipment (PPE) as an occupational safety

45   measure [1,2]. The use of PPE in terms of occupational safety requires trained handling of the

46   individual components of the PPE. In the context of the COVID-19 pandemic, the use of respirators was

47   also recommended for persons not specifically trained in their use in several countries and was even

48   made mandatory in some areas.

49   Whereas in many countries around the world mandatory protective measures imposed by the

50   government have been withdrawn, in Germany, curiously the regulations have been tightened even

51   further with a partial respirator obligation [3]. For a transmission-reducing effect a continuously

52   assured tight fit of respirators, achieve a seal of the mask to the face such that air cannot bypass

53   filtration via gaps between mask and wearer's face, has been described to be necessary [4]. That is

54   why a systematic literature search on this topic was recommended [5].

55   The tight fit of respirators can be determined in wearing persons with two different methods [6]. In

56   qualitative fit testing, different aerosolized flavors can be used and the subjects report whether they

57   can perceive the taste of the test substance nebulized inside a tight hood. The test is considered as

58   failed if the flavor is perceived while wearing the respirator [6]. If the flavor is not perceived with the

59   respirator in place, but is consciously perceived without the respirator, the test is considered to be

60   passed. Quantitative fit testing involves measuring the number of measurable particles outside and

61   inside the respirator while being worn. The calculated quotient is the fit factor [6]. For respirators

62   classified as FFP2 (European standard), N95 (US standard), KN95 (Chinese standard) and KF94 (South

63   Korean standard), a modified fit test is used compared to respiratory protective equipment with higher

64   protection levels with (e. g. FFP3 respirators). For FFP2 and similar respirators only a defined particle

65   size is determined in quantitative fit tests, which are typically almost completely retained by the

66   typically used filter material. When performing a quantitative fit test, the fit factors are continuously

67   measured during standardized movements and activities (normal breathing, deep breathing, turning

68   the head, raising and lowering the head, speaking, bending the upper body forward, and final normal

69   breathing) and subsequently an overall fit factor is determined. According to common occupational

70   health and safety standards, a correct fit of respirators is assumed if a fit factor of ≥100 is achieved

71   [1,6].

72   For disposable respirators (NR), the market offers a large number of different shape types (exemplary

73   selection in Fig. 1). Respirators can be differentiated according to their shape and the way in which the

74   respirator is attached to the head of the person wearing it. In terms of shape, dome shaped respirators,

75   which are rigidly preformed (Fig. 1 A) or three-panel folded (Fig. 1 B, C, H), are distinguished from

76   respirators consisting of only two folded planes, in which the fold seam runs horizontally (duckbill

77   shape, Fig. 1 D, E) or vertically (coffee filter shape, Fig. 1 F, G, I, J). In most industrialized countries,

78   respirators with head straps (Fig. 1 A to G) were widely used in healthcare before the onset of the

79   pandemic. In the case of fixation with head straps, a distinction is made between the principle of one

80   head strap that is movably deflected at the edges of the respirator (fig. 1 A, D, E, F) and two separately

81   attached upper and lower head straps of different lengths (fig. 1 B, C, G). With the onset of the

82   pandemic, respirators with ear loops (Fig. 1 H - J) were increasingly used in healthcare as well. In the

83   case of respirators with ear loops, the ear loops can be connected behind the head by using technical

84   aids (Fig. 1 H, I) and thus the respirator body can be fixed to the head of the person wearing it with

85   higher contact pressure. In the case of some respirators, the manufacturer already supplied these

86   technical aids during distribution, so that it must be assumed that the suitability testing was carried

87   out with the technical aid. Some respirators have an exhalation valve (Fig. 1 B, D, F), which considerably

88   reduces the airway resistance during exhalation at physically strenuous activities. For respirators with

89   an exhalation valve, it must be noted that patient protection is limited in the case of infectious

90   personnel, so that these types of respirators were not recommended during the SARS-CoV-2

91   pandemic.

92   The aim of our review was therefore to evaluate the results of quantitative fit tests stratified according

93   to different respirator types. Furthermore, we analyzed randomized controlled trials on the efficacy of

94   medical masks and respirators on the prevention of viral respiratory tract infections.

95

96   **Methods**

97   A Pubmed literature search was performed on 09/14/2022 using the terms "quantitative fit test" in

98   combination with "respirator", "FFP2", "N95", "KN95", KF94" or "mask". Due to the different methods

99   of fit testing respirators classified as FFP3 and the resulting poor comparability the term "FFP3" was

100   not used in the literature search. All publications identified with the search strategy, as well as

101   additional sources identified as appropriate during the literature review, were reviewed for clearly

102   evaluable information on the results of a quantitative fit test for individual respirator types. Only data

103   on disposable (NR) respirators that met the following minimum criteria were included for further

104   analysis:

105   • Standardized quantitative fit test with pass limit of a fit factor of ≥ 100

106   • Clear assignment of the results of the fit test to individual respirator types (information on

107   manufacturer and type designation or illustration of the respirator in the publication)

108   • At least two different subjects per respirator type

109   • Clear indication of the number of subjects with successful and failed fit tests

110   • Test results without modifications of the respirator or facial morphology

111   • Test results with first use of the respirator

112   • Testing in a medical context

113   From studies with testing of respirators under different conditions (e.g. repeated use, disinfection of

114   the respirators, testing with modified movement patterns, etc.) only the respective data sets were

115   included which fulfilled the above mentioned conditions. For all studies, only the overall results

116   (pass/fail or overall fit factor) were included in the analysis. Partial results of individual steps of the

117   quantitative fit tests were not included. In addition, mean or median values of the measured fit factors

118   were evaluated where available. In the following text, quantitative fit tests are referred to only as fit

119   tests for better readability.

120   Randomized controlled trials (RCTs) were reviewed for comparative evaluation of the efficacy of

121   respirators and surgical masks for the prevention of viral respiratory infections. A search was

122   conducted on PubMed on 10/17/2022 using the terms "N95 randomized controlled" as well as "FFP

123   randomized controlled." Studies were included if they were RCTs that directly compared rates of viral

124   respiratory infections between wearers of surgical masks and respirators in healthcare settings and if

125   participants in the group with respirators had performed at least one qualitative fit test before the

126   start of the study and had thus demonstrably successfully passed a fit test. Studies were excluded if

127   the effect was examined in the home setting or if only respirator were examined.

128

129

130 **Results**

131 Fit Tests with respirators

132 The search strategy for quantitative fit tests identified a total of 29 studies (Fig. 2 A), which presented

133 information on the pass and fail rates of the respective group of tested respirators for clearly

134 assignable types (Table 1 and tables in the Appendix). In 15 studies, it was also possible to obtain clear

135 information on the mean and/or median of the values determined for the fit factors, but their

136 evaluated values cannot be representative for all studies conducted (details see supplementary

137 tables). In 15 studies, data were collected on three-panel folded respirators with head straps for a total

138 of 4625 fit tests (Tables 1 and S1). For this respirator type, 80.8% of initial fit tests were passed. The

139 mean values of the fit factors for this respirator type ranged from 141.5 to 220.9 (6 studies, 2097 fit

140 tests). The median could only be determined for 3 studies and ranged from 139 to 200 (28 fit tests).

141 Rigid respirators (dome shape) with head straps showed a pass rate of 72.4% (20 studies, 8234 fit

142 tests). The mean values of the fit factors ranged from 4.8 to 187.8 (10 studies, 402 fit tests) and the

143 median ranged from 5.6 to 200 (5 studies, 58 fit tests). Rigid respirator with low fit factors were most

144 common among infrequently tested manufacturers (Tables 1 and S2). Duckbill shaped respirators with

145 head straps (Tables 1 and S3) had a 31.6% pass rate of fit tests (11 studies, 2120 fit tests). The mean

146 values of the fit factors ranged from 29 to 152.7 (4 studies, 80 fit tests) and the median ranged from

147 21 to 145 (3 studies, 202 fit tests). Respirators with coffee filter shape and head straps (Tables 1 and

148 S4) showed a pass rate of fit tests of 30.9% (4 studies, 3392 fit tests). Only in one study with 407 fit

149 tests were mean values of the fit factors of this respirator type available from different manufacturers,

150 ranging from 13.5 to 110.7.

151 For respirators with ear loops, only five studies with a total of 222 fit tests were found on respirators

152 with coffee filter shape (n=60, Tables 1 and S5) and three-panel folded dome shaped respirators

153 (n=162, Tables 1 and S6). Overall, only 3.6% of the fit tests were passed (8.3% for dome shaped

154 respirators, 1.9% for coffee filter shaped respirators). The mean and median fit factors of three-panel

155 folded respirators with ear loops were 43 (1 study, 60 fit tests). The mean values of the fit factors

156 ranged from 2.2 to 11.4 for respirators with coffee filter shape (4 studies, 132 fit tests). The median

157 ranged from 3 to 39 (1 study, 90 fit tests). Interestingly, in this study [7], a three-panel folded

158 respirator with the ability to adjust the length of the ear loops on the respirator performed relatively

159 better (median 39, vs. 3 and 4 for nonadjustable ear loops). However, even for the respirator with

160 adjustable loop length, the fit test was passed in only 4 of 30 cases.

161

162 RCTs on the protective effect of respirators and surgical masks

163 With the search strategy conducted on randomized comparative studies of the effectiveness of

164 medical masks and respirators for the prevention of viral respiratory infections in healthcare workers,

165 a total of 4 studies were identified (Fig. 2 B, Tables 2). For three studies, there was clear information

166 on the types of respirators used [8–10]. In these studies, only respirators with head straps but different

167 respirator body shapes were used. In the fourth paper, no information was given on the respirator

168 type. However, it can be assumed that respirators of high quality were also used, since only subjects

169 who passed a fit test were included in the respirator group.

170 Two studies considered the incidence of laboratory-confirmed influenza as the primary end point and

171 the incidence of other respiratory infections as secondary end points [10,11]. Two papers evaluated

172 multiple forms of respiratory infections as primary endpoints [8,9]. None of the studies showed

173 superiority of tight fitting respirators (by fit test) over surgical masks for the endpoints of laboratory-

174 confirmed influenza, laboratory-confirmed viral respiratory infections, and influenza-like respiratory

175 infections. Two studies [8,9] showed, in part, a significantly lower number of cases in the continuously

176 worn respirator groups versus the surgical mask groups for the clinical respiratory tract infection

177 endpoint. Interestingly, in a study with two respirator groups (with and without a fit test), this

178 observation was made only for the wearers of respirators without a fit test but not for the wearers of

179 respirators with a fit test [9]. In a *post hoc* analysis to exclude confounding factors, when both groups

180 of respirators (with and without fit test) were combined in this study [9], there was a comparable

181 significant reduction in the endpoints of laboratory-confirmed viral respiratory tract infections and

182   clinical respiratory tract infections for the comparison groups of all respirators and surgical mask for

183   the type of facility ("hospital level") and type of face cover used.

184

185

186 **Discussion**

187 From the point of view of occupational health and safety requirements, the most important factor for

188 the protection of a person by wearing a disposable respirator is the tight fit of the respirator [1,2], even

189 during physical activity, which is associated with the protective effect. In the technical development,

190 approval and quality control of disposable respirators, a standardized pliable elastomeric head form is

191 regularly used (Sheffield dummy head), which represents male European facial dimensions [12,13].

192 This dummy does not represent the diversity of people working in the healthcare sector around the

193 world including their variable head forms and is likely to have a non-negligible effect on fit test results

194 of commercially available respirators. Only few efforts were made to overcome these problem in the

195 laboratory testing of respirators [13–15].

196 The tight fit of respirators during patient care or other movements of the head depends on many

197 different factors such as the shape of the face [16,17], the presence of beards, stubble or any hair in

198 the region where a face mask seals [18,19], the knowledge of the person using the respirator, and the

199 shape of the respirator. An important aspect of the tight fit of a respirator is also the way in which the

200 respirator is fixed to the head of the person wearing it. Before the pandemic, (almost) exclusively

201 respirators with head straps were used in medical facilities, whereas since the initial shortage of

202 respirators was eliminated at the beginning of the pandemic, the market has been dominated by

203 respirators with ear loops (own observation). It should be noted here that in the scientific literature

204 with studies conducted before the pandemic with respirators of the N95 and KN95 type with coffee

205 filter shape, this shape type was also used, but with head straps that were often adjustable in length

206 to the head size.

207 The data collected in the studies included in this review indicate a relative superiority of dome shaped

208 respirators (three-panel folded or rigidly shaped; figs. 1 A-C) with head straps compared with

209 respirators consisting of two folded planes (duckbill shape, or coffee filter shape, figs. 1 D-G) with the

210 same type of attachment. The superiority of three-panel folded respirators compared to other shape

211 types could also be traced in a number of other studies, which could not be included in this review due

212   to lack of partial data [20–23]. A clear inferiority was shown for respirators with ear loops compared

213   to respirators with head straps as the attachment type. In another study, which was not included

214   because of the criteria selected, all respirators tested with ear loops failed an upstream qualitative fit

215   test, in contrast to respirators with head straps, so no quantitative fit test was included in the study

216   [24]. Indirectly, however, this study demonstrated an inadequate tight fit for an additional 12

217   respirators of the coffee filter shape with ear loops from different manufacturers. The disadvantage of

218   fastening respirators by ear loops was confirmed experimentally by converting some respirators from

219   fastening by means of head straps to length-adjustable ear loops with the respirator body remaining

220   unchanged, and subsequently an adequate tight fit could no longer be achieved despite the ear loops

221   being adjustable to the anatomy [25]. For this reason, some governmental occupational safety

222   organizations indicate that respirators with ear loops do not provide adequate protection as tight

223   fitting respiratory protective equipment [26].

224   The regulations imposed by the governments in individual countries for the prevention of public health

225   problems during the pandemic now vary widely. They range from the abolition of mandatory

226   requirements to the mandatory wearing of respirators in individual areas of society. In Germany, the

227   assessment that a temporary respirator mandate represents an effective and rapid instrument for

228   infection control was justified [4], among other things, by a review paper which, on the basis of the

229   evaluation of six studies, states that a mandate for face covering masks leads to a median reduction in

230   incidence of 53% [27]. Interestingly, this review, citing a review published in 2016, claims that

231   respirators (N95 or similar respirator) achieved greater effectiveness compared with a surgical masks,

232   whereas the paper cited as supporting evidence [28] clearly highlights that there was no significant

233   difference in the prevention of respiratory tract infections with use of respirators or surgical masks by

234   healthcare professionals. The lack of superiority of respirators over surgical masks in the prevention of

235   viral respiratory infections in health care workers was demonstrated in four randomized trials

236   identified in this paper [8–11], although they involved personnel specifically trained in the use of

237   respirators (with fit test performed). This observation was confirmed by a recent study, which also

238   failed to observe superiority of respirators over masks for the acquisition of COVID-19 [29]. The

239 conclusion drawn from some experts that respirators should be preferred from an infection prevention

240 point of view for external and self-protection, especially in risk settings such as medical or nursing

241 areas [5], is therefore not comprehensible, at least on the basis of data with persons wearing

242 respirators. This is particularly supported by a recent review which concluded that there is no

243 advantage of respirators over surgical masks for preventing transmission of SARS, but that there may

244 be side effects from the greater stress [30].

245 Due to the search and inclusion criteria, the review study addresses only the tight fit in terms of self-

246 protection of respirator wearers, as quantitative fit tests only examine this issue. However, the

247 literature review also provided evidence that respirators may be inferior to even a surgical masks in

248 terms of extraneous protection (reducing the release of secretions and aerosols from the upper

249 airway). A recent study showed that surgical masks as well as respirators significantly reduced

250 emissions during breathing, speaking, coughing, and chewing. However, surgical masks showed a 90%

251 reduction in outward emissions compared with wearing no mask, whereas respirators showed a mean

252 reduction of only 74% [31]. A test of restraint for external protection also showed inferiority of a dual-

253 fold respirator with ear loops compared with a respirator with head straps but also a surgical mask

254 [32]. As early as 2008, a study was able to show that, in contrast to significantly different protective

255 effects during inhalation between respirators (with head straps) and surgical mask, no significant

256 differences were observed in the external protective effect during exhalation [33]. One major paper

257 that was used to justify the efficacy of general respirator use was a mathematical-theoretical model

258 that calculated the best protection when using highly tight-fitted respirators on the index person and

259 a contact person [34]. However, this work equated inhalation and exhalation leakage for the

260 mathematical model. At most, this assumption can be adopted for an extremely tight-fitting respirator

261 because exhalation creates positive pressure in the respirator body, whereas inhalation creates

262 negative pressure. For respirators with ear loops, it can be assumed with a very high probability that

263 the majority of exhaled air exits unfiltered at the edges of the respirator. This assumption was also

264 supported by visualization in one study [35].

265   The respirators investigated in the included studies were exclusively single-use (NR), which are not

266   approved for repeated use. For persons trained in the use of respirators, a self-test at the beginning of

267   use can help to improve the fit of the respirator [23]. However, even with successful fit testing, an

268   optimal fit is not guaranteed for all types of activities. For example, several studies have shown that

269   airtight fit is not continuously maintained during typical patient care activities [36,37]. These

270   observations may be part of the explanation for why no difference in the prevention of viral respiratory

271   infections was observed between respirators and surgical masks in randomized controlled trials, even

272   among well-trained health care workers. The fact that in a post hoc analysis in one study, the hospital

273   level showed a comparable significant reduction in the endpoints of laboratory-confirmed viral

274   respiratory tract infections and clinical respiratory tract infections points to the importance of training

275   individuals in the use of respirators. A RCT on the effectiveness of respirators compared surgical masks

276   in households did not show a greater effectiveness of respirators over surgical masks or any reduction

277   at all compared with households without mask use [38]. However, household members with use of

278   surgical masks or respirators reported adherence to wearing the face covering of less than 50% in both

279   groups already at the beginning of events, which decreased during the course and decreased more for

280   respirators during the course compared with wearing a surgical mask. It is therefore reasonable to

281   assume that, particularly for those not adequately trained in their use, leakage increases with

282   prolonged wear due to body and facial movement, and overall compliance to correct respirator use in

283   the home environment is low. Repeated use of respirators for occupational health and safety is not

284   recommended based on the observation that even with very high-quality respirators with an optimal

285   fit, simulated multiple use decreases the protective effect [39,40]. Reuse of a respirator after removal

286   should therefore only occur in exceptional cases and only by personnel specially trained in the donning

287   and doffing process of respirators. This should only be applied to high-quality, well-fitting respirators

288   with head straps. According to existing studies, the multiple use of a respirator with ear loops should

289   be strictly rejected for all users because of an assumed further reduction of an already low protective

290   effect.

291   The review has some limitations. The chosen search strategy does not fully ensure that all publications

292   on the topic of fit testing using quantitative fit tests were identified. Since in the USA and Canada fit

293   tests are mandatory for respirator wearers, the included studies are dominated by respirator types

294   that are most common in North America. Therefore, the statements on the superiority of three-panel

295   folded respirators cannot be generalized, since a few individual manufacturers dominate for almost all

296   respirator types and comparable respirator types from other manufacturers can perform significantly

297   differently in fit tests for the same shape. This is also indicated by the sometimes significantly worse

298   pass rates and fit factors of individual rarer respirator brands in other respirator types. Therefore,

299   further comparative studies on the fit of comparable respirator types from different manufacturers

300   should be conducted. Since only particle sizes that are optimally suited for the detection of leakage at

301   the respirator-skin contact surface are recorded during the fit testing of disposable respirator, no direct

302   conclusion can be drawn regarding the risk of infection by viral pathogens. Respirators classified as

303   FFP3 are recommended in some countries such as the UK. But they were not addressed in this review

304   because the method for their facial fit testing is different. In the randomized studies included in the

305   review, only a qualitative fit test was performed in three papers and no information on the type of fit

306   test is available for one paper. Therefore, it cannot be excluded that these studies would come to

307   different results if quantitative fit tests were performed.

308

309   **Conclusion**

310   Mandates to use respirators for untrained individuals outside of medical facilities as well as the

311   continuous use in hospitals lack evidence and should be withdrawn. Respirators should only be used

312   for specific occupational indications and after instruction in their effective use. Based on current

313   evidence the mandatory use of respirators in selected settings to prevent viral transmission cannot be

314   justified. Further studies should be performed to generate evidence in which scenarios the use of

315   respirators provide an effective benefit for medical personnel as part of occupational health and

316   safety. In situations with confirmed benefits only high-quality respirators with head straps or

317   respiratory protective equipment of higher protective levels should be used for well-trained personnel.

318

Conflict of interests

The authors declare that there is no conflict of interest. The views expressed herein are those of the

authors and do not necessarily reflect those of the universities with which they are affiliated.

322

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460

461

462 **Figure legends**

463

464 **Figure 1** Exemplary shape types of disposable respirators. Dome-shaped respirators, which are rigidly

465 preformed (**A**) or three-panel folded (**B**, **C**, **H**), as well as respirators consisting of two folded planes in

466 which the fold seam runs horizontally (duckbill shape, **D**, **E**) or vertically (coffee filter shape, **F**, **G**, **I**, **J**)

467 are displayed. The respirators can be fixed to the head of the person wearing them with head straps

468 (**A** - **G**) or ear loops (**H** - **J**). In the case of head straps, one single head strap can be movably deflected

469 at the edges of the mask (**A**, **D**, **E**, **F**) or head straps of different lengths are attached (**B**, **C**, **G**). For

470 respirators with ear loops, technical aids can be used to connect the ear loops behind the head (**H**, **I**).

471 Another important distinguishing criterion is the presence of an exhalation valve (**B**, **D**, **F**).

472

473 **Figure 2** Flow charts illustrating the search strategies for the review. The search strategies for

474 evaluating quantitative fit tests (**A**) and for RCTs comparing medical masks and FFP masks (**B**) are

475 displayed.

Type of respirator	Type of fixation	Number of studies	Number of QNFT[a]	Overall pass rate QNFT[a]	mean[b] (number QNFT / studies)	median[b] (number QNFT / studies)
three-panel folded respirator (dome-shape)	head straps	15	4625	80.8 %	141.5 – 220.9 (2097 / 6)	139 – 200 (28 / 3)
rigid respirator (dome-shape)	head straps	20	8234	72.4 %	4.8 – 187.8 (402 / 10)	5.6 – 200 (58 / 5)
respirator with "duckbill"-shape	head straps	11	2120	31.6 %	29 – 152.7 (80 / 4)	21 – 145 (202 / 3)
respirator with "coffee filter"-shape	head straps	4	3392	30.9 %	13.5 – 110.7 (407 / 1)	-
three-panel folded respirator (dome-shape)	earloops	1	60	8.3 %	43 (60 / 1)	43 (60 / 1)
respirator with "coffee filter"-shape	earloops	5	162	1.9 %	2.2 – 11.4 (132 / 4)	3 – 39 (90 / 1)

[a]QNFT: quantitative fit test

[b]Mean/median refers to the indicated values of the fit factors of the individual studies if indicated; the values might not be representative for all studies (details see supplementary tables)

Table 2 results of randomized clinical trials

| source	departments (number of hospital)	usage	surgical mask				N95 respirator					P-value
			type / manufacturer	endpoint[a]	cases	number	type / manufacturer	fit test passed	endpoint[a]	cases	number	
Loeb et al. 2009 (30)*	Emergency departments, medical and pediatric wards (8)	Targeted use of surgical mask or respirator during activities with persons with febrile respiratory infections	unknown	LCI[b]	50	212	unknown	100%	LCI[b]	48	210	0.86
				LCV[c]	20	212			LCV[c]	22	210	0.72
				ILI	9	212			ILI	2	210	0.06
				CRI[d]	13	212			CRI[d]	13	210	0.98
MacIntyre et al. 2011 (31)	Emergency departments, pulmonology wards (15)	Surgical masks or respirator (with and without fit test) worn throughout shift (average wear time 4.9 to 5.2 hours)	type 1820 / 3M	LCI	5	492	type 9132 / 3M	98.9%	LCI	3	461	0.54
				LCVI	13	492			LCVI	8	461	0.50
				ILI	3	492			ILI	1	461	0.37
				CRI	33	492			CRI	21	461	0.60
			type 1820 / 3M	LCI	5	492	type 9132 / 3M	not perfomed	LCI	0	488	-
				LCVI	13	492			LCVI	5	488	0.11
				ILI	3	492			ILI	2	488	0.66
				CRI	33	492			CRI	16	488	<0.05
MacIntyre et al. 2013 (32)	Emergency departments, pulmonology wards (19)	Surgical masks or respirator worn throughout shift Surgical masks worn throughout shift;	type 1817 / 3M	LCI	1	572	type 1860 / 3M	97.4%	LCI	3	581	0.32
				LCVI	19	572			LCVI	13	581	0.44
				ILI	4	572			ILI	6	581	0.54
				CRI	98	572			CRI	42	581	<0.05
		targeted use for respirators	type 1817 / 3M	LCI	1	572	type 1860 / 3M	97.4%	LCI	2	516	0.59
				LCVI	19	572			LCVI	17	516	0.99
				ILI	4	572			ILI	2	516	0.49
				CRI	98	572			CRI	61	516	0.28
Radonovich et al. 2019 (33)	Outpatient departments, emergency rooms (7)	Surgical mask or respirator throughout shift with self-assessment of adherence to the measure	type 15320 / Precept, as well as type 47107 / Kimberley Clark	LCI	193	2668	types 1860. 1860S, and 1870 / 3M, as well as types PFR95-270 and PFR95-274 / Kimberley Clark	not described	LCI	207	2512	0.18
				LCVI	417	2668			LCVI	371	2512	0.39
				ILI	166	2668			ILI	128	2512	0.08
				CRI	1711	2668			CRI	1556	2512	0.10

[a] LCI: laboratory confirmed influenza; LCVI: laboratory confirmed virus; ILI: influenza like illness; CRI: clinical respiratory illness
[b] In this study, defined as detection by PCR or an at least a 4-fold increase in serum antibodies to circulating influenza strain antigens
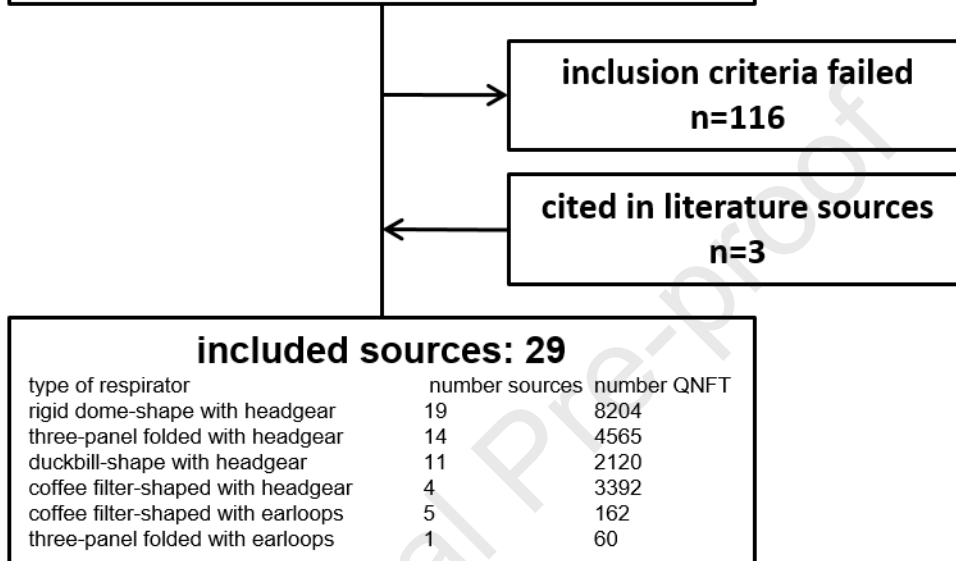[c] In this study, defined as the detection of other viral respiratory pathogens by PCR.
[d] In this study, defined as a visit to a physician for a respiratory infection
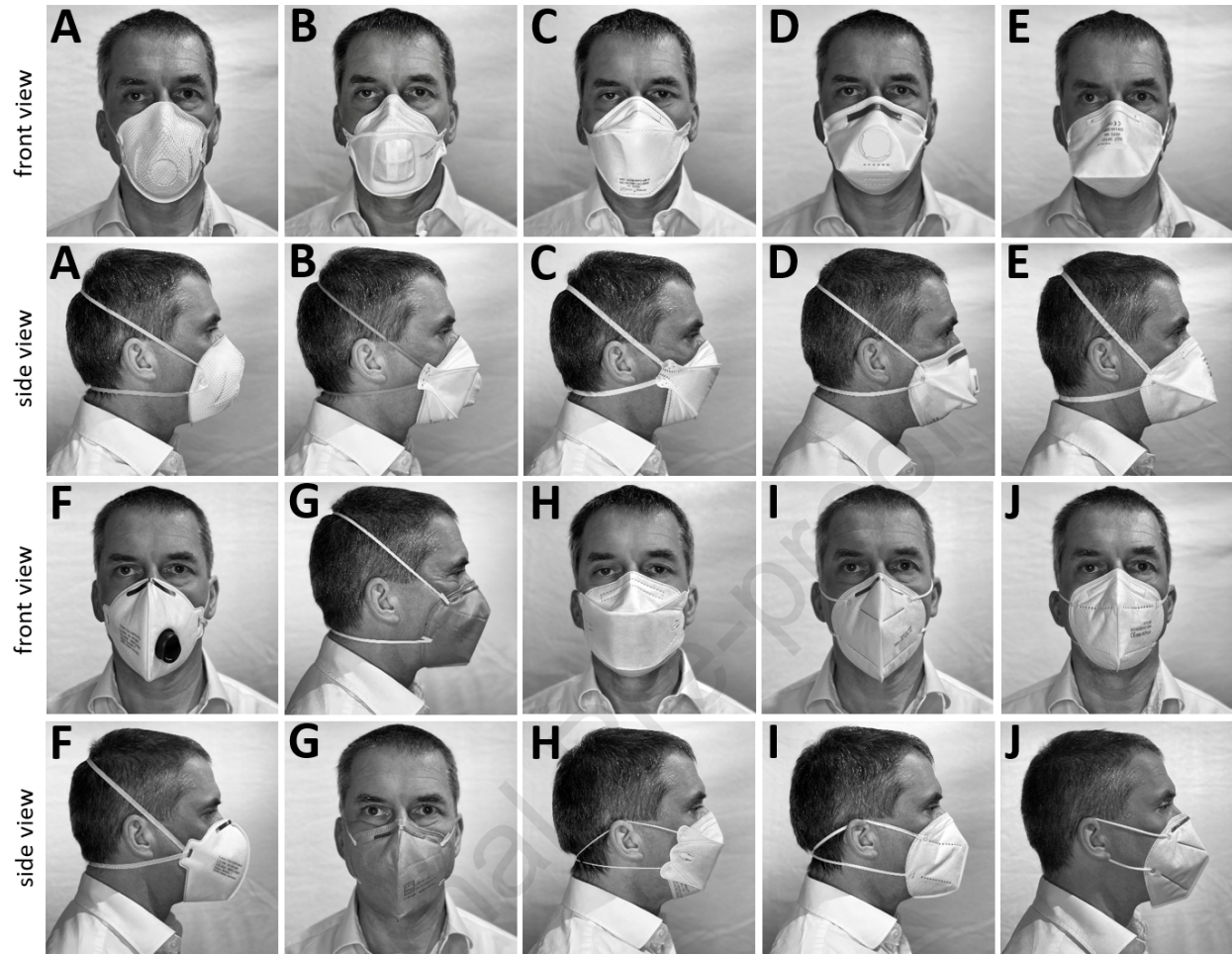
A

search strategy

search term	number sources	additional sources
respirator quantitative fit test	131	
N95 quantitative fit test	80	3
KN95 quantitative fit test	6	0
FFP2 quantitative fit test	5	0
KF94 quantitative fit test	2	0
mask quantitative fit test	84	8

sources total: 142

inclusion criteria failed
n=116

cited in literature sources
n=3

included sources: 29

type of respirator	number sources	number QNFT
rigid dome-shape with headgear	19	8204
three-panel folded with headgear	14	4565
duckbill-shape with headgear	11	2120
coffee filter-shaped with headgear	4	3392
coffee filter-shaped with earloops	5	162
three-panel folded with earloops	1	60

B

search strategy

search term	number sources
N95 randomized controlled	101
FFP2 randomized controlled	19

sources total: 120

inclusion criteria failed

reason	number sources
duplicates	10
sources with followig updates	4
only data for respirators	3
RCT for bacterial contamination	1
reviews	26
other topics	72

n=116

included sources: 4